



Docket No.: 0425-1154PUS1  
(PATENT)

*[Handwritten signatures]*

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:  
Norihito OHI et al.

Application No.: 10/509,795

Confirmation No.: 9627

Filed: February 25, 2005

Art Unit: 1626

For: PYRAZOLE COMPOUNDS AND  
PHARMACEUTICAL COMPOSITIONS  
COMPRISING THE COMPOUND

Examiner: J. M. Nolan

### INFORMATION DISCLOSURE STATEMENT (SUBMISSION AFTER FILING OF AN APPLICATION BUT BEFORE FINAL REJECTION OR NOTICE OF ALLOWANCE OR CONCURRENTLY WITH A RULE 1.114 RCE APPLICATION)

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

02/09/2007 MBERHE 00000164 10509795  
01 FC:1806 180.00 OP

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner.

#### I. LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION

The patents, publications, or other information submitted for consideration by the Office are listed on the PTO-SB08(s), attached hereto.

#### II. COPIES

- a. Copies of cited U.S. patents and patent application publications are not included.  
Copies of foreign patent documents and non-patent literature are included.

- b. Some or all of the documents listed on the PTO-SB08 are not enclosed because they were cited in the International Search Report and copies should already be in the PTO file. If copies are needed, please contact the undersigned.
- c. REFERENCES PREVIOUSLY CITED OR SUBMITTED - Pursuant to 37 C.F.R. §1.98(d), consideration of information listed on the PTO-SB08 form(s) is requested since any patents, publications, or other information which are listed on the PTO-SB08 form(s) but for which copies are not enclosed herewith, were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. § 120:

U.S. Appl. No(s) and U.S. Filing Date

@@@ filed @@@

III. CONCISE EXPLANATION OF THE RELEVANCE

(check at least one box)

- a. DOCUMENTS IN THE ENGLISH LANGUAGE - The patents, publications, or other information listed on the attached PTO SB08 are in the English language and therefore, do not require a statement of relevancy.
- b. DOCUMENTS NOT IN THE ENGLISH LANGUAGE - A concise explanation of the relevance of all patents, publications, or other information listed that is not in the English language is as follows:
- c. ENGLISH LANGUAGE SEARCH REPORT - An English language version of the search report or action that indicates the degree of relevance found by the foreign office is attached, thereby satisfying the requirement for a concise explanation. See MPEP 609(III)(A)(3).
- d. OTHER - The following additional information is provided for the Examiner's consideration.

IV. FEES (check one box)

- a. This Information Disclosure Statement is being filed concurrently with the filing of a new patent application; therefore, no fee is required.
- b. This Information Disclosure Statement is being filed concurrent with the filing of a continuation-in-part, continuation, or divisional patent application; therefore, no fee is required.
- c. This Information Disclosure Statement is being filed within three months of the filing date of a national application (37 C.F.R. § 1.97(b)(1)). No fee or statement is required.  
*(This section is not to be used with RCE's.)*
- d. This Information Disclosure Statement is being filed within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. § 1.97(b)(2)). No fee or statement is required.
- e. This Information Disclosure Statement is being filed concurrently with the filing of a Request for Continued Examination under § 1.114 (37 C.F.R. § 1.97(b)(4)). No fee or statement is required.
- f. This Information Disclosure Statement is being filed before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or statement is required. In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the statement under 37 C.F.R. § 1.97(e) below, or, if no statement has been made, charge our deposit account for the fee as required by 37 C.F.R. § 1.17(p).
- g. This Information Disclosure Statement is being filed before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c)(1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c)(2)).
- No statement; therefore, a fee as required by 37 C.F.R. § 1.17(p) is attached.

or

See the statement below. No fee is required.

V. STATEMENT UNDER 37 C.F.R. § 1.97(e)

(check only one box)

The undersigned hereby states that:

- a. Each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than 30 days prior to the filing of this IDS; or
- b. Each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
- c. No item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the IDS.
- d. Some of the items of information were cited in a communication from a foreign Patent Office. As to this information, the undersigned states that each item of information contained in the IDS was first cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby states that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application and, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

VI. PAYMENT OF FEES (check one box)

- The required fee is listed on the attached Fee Transmittal.  
 No fee is required.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule and charge the appropriate fee to Deposit Account No. 02-2448.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated: February 8, 2007

Respectfully submitted,

  
By \_\_\_\_\_  
RG  
Marc S. Weiner  
Registration No.: 32,181  
BIRCH, STEWART, KOLASCH & BIRCH, LLP  
8110 Gatehouse Road  
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P.O. Box 747  
Falls Church, Virginia 22040-0747  
(703) 205-8000  
Attorney for Applicant

Attachment(s):

- PTO-SB08  
 Documents  
 Foreign Search Report  
 Fee  
 Other:



Under the Paperwork Reduction Act of 1995, no person are required to respond to a collection of information unless it displays a valid OMB control number.

**Effective on 12/08/2004.**  
**Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).**

## FEE TRANSMITTAL For FY 2006

Applicant claims small entity status. See 37 CFR 1.27

<b>TOTAL AMOUNT OF PAYMENT</b>	(\$)	180.00
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<b>Complete if Known</b>	
Application Number	10/509,795-Conf. #9627
Filing Date	February 25, 2005
First Named Inventor	Norihito OHI
Examiner Name	J. M. Nolan
Art Unit	1626
Attorney Docket No.	0425-1154PUS1

### METHOD OF PAYMENT (check all that apply)

Check    Credit Card    Money Order    None    Other (please identify): \_\_\_\_\_  
 Deposit Account   Deposit Account Number: 02-2448   Deposit Account Name: Birch, Stewart, Kolasch & Birch, LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

Charge fee(s) indicated below    Charge fee(s) indicated below, except for the filing fee  
 Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17    Credit any overpayments

### FEE CALCULATION

#### 1. BASIC FILING, SEARCH, AND EXAMINATION FEES

<u>Application Type</u>	<u>FILING FEES</u>		<u>SEARCH FEES</u>		<u>EXAMINATION FEES</u>		<u>Fees Paid (\$)</u>
	<u>Fee (\$)</u>	<u>Small Entity Fee (\$)</u>	<u>Fee (\$)</u>	<u>Small Entity Fee (\$)</u>	<u>Fee (\$)</u>	<u>Small Entity Fee (\$)</u>	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

#### 2. EXCESS CLAIM FEES

##### Fee Description

Each claim over 20 (including Reissues)

<u>Fee (\$)</u>	<u>Small Entity Fee (\$)</u>
50	25
200	100
360	180

Each independent claim over 3 (including Reissues)

Total Claims   Extra Claims   Fee (\$)   Fee Paid (\$)

71 - 71 = x =   
HP = highest number of total claims paid for, if greater than 20.

Indep. Claims   Extra Claims   Fee (\$)   Fee Paid (\$)

3 - 3 = x =   
HP = highest number of independent claims paid for, if greater than 3.

#### 3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

<u>Total Sheets</u>	<u>Extra Sheets</u>	<u>Number of each additional 50 or fraction thereof</u>	<u>Fee (\$)</u>	<u>Fee Paid (\$)</u>
- 100 =	/50	(round up to a whole number) x	=	

#### 4. OTHER FEE(S)

Non-English Specification, \$130 fee (no small entity discount)

Other (e.g., late filing surcharge): 1806 Submission of an Information Disclosure Statement   180.00

<u>SUBMITTED BY</u>		<u>Registration No. (Attorney/Agent)</u>	<u>Telephone</u>
Signature	<u>Marc S. Weiner</u>	32,181	(703) 205-8000
Name (Print/Type)	Marc S. Weiner	Date	February 8, 2007



PTO/SB/08A/B (09-06)

Approved for use through 03/31/2007. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449/PTO				<b>Complete if Known</b>	
				Application Number	10/509,795-Conf. #9627
				Filing Date	February 25, 2005
				First Named Inventor	Norihiro OHI
				Art Unit	1626
				Examiner Name	J. M. Nolan
Sheet	1	of	2	Attorney Docket Number	0425-1154PUS1

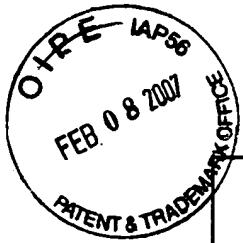
U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)			
BA	WO-00/35909-A1		06-22-2000		
BB	WO-00/35921-A1		06-22-2000		
BC	WO-00/64872-A1		11-02-2000		
BD	WO-00/35906-A2		06-22-2000		
BE	WO-00/75118-A1		12-14-2000		
BF	WO-01/12609-A1		02-22-2001		
BG	WO-01/12621-A1		02-22-2001		
BH	WO-01/23378-A1		04-05-2001		✓
BI	WO-01/23379-A1		04-05-2001		
BJ	WO-01/23382-A1		04-05-2001		
BK	EP-1 110 957-A1		06-27-2001		✓
BL	WO-01/91749-A1		12-06-2001		✓
BM	WO-02/10137-A2		02-07-2002		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			
CA	Kyriakis et al.; "The stress-activated protein kinase subfamily of c-Jun kinases"; Letter to Nature, vol. 369, pp 156-160, 1994				
CB	Xia et al.; "Opposing Effects of ERK and JNK-p38 MAP Kinases on Apoptosis"; Science, vol. 270, pp. 1326-1331, 1995				
CC	Pulverer et al.; "Phosphorylation of c-jun mediated by MAP kinases"; Letters to Nature, vol. 353, pp. 670-674, 1991				
CD	Gupta et al.; "Selective interaction of JNK protein kinase isoforms with transcription factors"; The Embo Journal, vol. 15, no. 11, pp. 2760-2770, 1996				
CE	Mohlt et al.; "p49 <sup>GF12</sup> Kinase: A Novel MAP Kinase Expressed in a Subset of Neurons in the Human Nervous System"; Neuron, vol. 14, pp. 67-78, 1995				
CF	Kuan et al.; "The Jnk1 and Jnk2 Protein Kinases Are Required for Regional Specific Apoptosis during Early Brain Development"; Neuron, vol. 22, pp. 667-676, 1999				

Examiner Signature	Date Considered
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Substitute for form 1449/PTO				Complete if Known	
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Sheet	2	of	2	Attorney Docket Number	0425-1154PUS1

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T <sup>2</sup>
	CG	Sabapathy et al.; c-Jun NH <sub>2</sub> -Terminal Kinase (JNK)1 and JNK2 Have Similar and Stage-dependent Roles in Regulating T Cell Apoptosis and Proliferation"; J. Exp. Med., vol. 193, no 3, pp. 317-328, 2001		
	CH	Hirosumi et al.; "A central role for JNK in obesity and insulin resistance"; Nature, vol. 420, pp. 333-336, 2002		
	CI	Yang et al.; "Absence of excitotoxicity-Induced apoptosis in the hippocampus of mice lacking the Jnk3 gene"; Letters to Nature, vol. 389, pp. 865-870, 1997		
	CJ	Ham et al.; "A c-Jun Dominant Negative Mutant Protects Sympathetic Neurons against Programmed Cell Death"; Neuron, vol. 14, pp. 927-939, 1995		
	CK	Watson et al.; "Phosphorylation of c-Jun Is Necessary for Apoptosis Induced by Survival Signal Withdrawal in Cerebellar Granule Neurons"; The Journal of Neuroscience, vol. 18, pp. 751-762, 1998		
	CL	Yuan et al.; "Apoptosis in the nervous system"; Nature, vol. 407, pp. 802-809, 2000		
	CM	Xia et al.; "Gene transfer of the JNK interacting protein-1 protects dopaminergic neurons in the MPTP model of Parkinson's disease"; PNAS, vol. 98, no. 18, pp. 10433-10438, 2001		
	CN	Savage et al.; "Activation of c-Jun N-Terminal Kinase and p38 in an Alzheimer's Disease Model is Associated with Amyloid Deposition"; The Journal of Neuroscience, vol. 22, pp. 3376-3385, 2002		
	CO	Zhu et al.; "Activation and redistribution of c-Jun N-terminal kinase/stress activated protein kinase in degenerating neurons in Alzheimer's disease"; Journal of Neurochemistry, vol. 76, pp. 435-441, 2001		
	CP	Bonni et al.; "Cell Survival Promoted by the Ras-MAPK Signaling Pathway by Transcription-Dependent and -Independent Mechanisms"; Science, vol. 286, pp. 1358-1362, 1999		
	CQ	Han et al.; "BDNF Protects the Neonatal Brain from Hypoxic-Ischemic Injury <i>In Vivo</i> via the ERK Pathway"; The Journal of Neuroscience, vol. 20, pp. 5775-5781, 2000		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	Date Considered
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(PATENT)

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In re Patent Application of:  
Norihito OHI et al.

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COMPRISING THE COMPOUND

Examiner: J. M. Nolan

**LETTER SUBMITTING COPIES OF PREVIOUSLY CITED DOCUMENTS**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

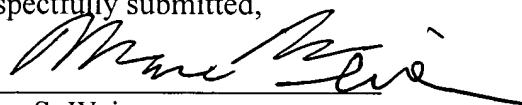
Sir:

Enclosed herewith are copies of the documents that were cited in the International Search Report and listed on the Form PTO-SB08 filed with the Information Disclosure Statement on September 29, 2004. The PTO is requested to make these documents of record in the file of the present application and to return the initialed Form PTO-SB08 to the undersigned.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated: February 8, 2007

Respectfully submitted,

By 

Marc S. Weiner

Registration No.: 32,181

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Suite 100 East

P.O. Box 747

Falls Church, Virginia 22040-0747

(703) 205-8000

Attorney for Applicant

Attachments: 1) Documents cited  
in Search Report (19); and  
2) copy of PTO-SB 08

COPY

PTO/SB/08a/b (08-03)

Approved for use through 07/31/2006. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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<p align="center">Substitute for form 1449A/B/PTO</p> <p align="center"><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b></p> <p align="center"><i>(Use as many sheets as necessary)</i></p>				<b>Complete if Known</b>	
				Application Number	Not Yet Assigned
				Filing Date	September 29, 2004
				First Named Inventor	Norihiro OHI
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	1	of	1	Attorney Docket Number	0425-1154PUS1

<b>U.S. PATENT DOCUMENTS</b>					
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		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)			
BA**	EP-594001-A1		04-27-1994		
BB**	EP-239191-A1		09-30-1987		
BC**	JP-1-190681-A		07-31-1989		
BD**	SU-1147712-A1		03-30-1985		
BE**	WO-02/083648-A1		10-24-2002		
BF**	WO-00/56710-A1		09-28-2000		
BG**	WO-99/20624-A1		04-29-1999		
BH**	WO-99/7705-A1		02-18-1999		
BI**	WO-98/52948-A1		11-26-1998		

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<b>NON PATENT LITERATURE DOCUMENTS</b>					
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T <sup>2</sup>
	CA**	Abdel-Aziz El-Taweel et al., Alexandria Journal of Pharmaceutical Sciences, (1998), 12(1), 11-15			
	CB**	Ghozlan, S.A.S. et al., Egyptian Journal of Pharmaceutical Sciences, (1992), 33(5-6), 859-67			
	CC**	Marei, Mohamed Gaber, Bulletin of the Chemical Society of Japan, (1993), 66(4), 1172-5			
	CD**	Rusinov, V.L. et al., Khimiya Geterotsiklicheskikh Soedinenii, (1992), (11), 1560-4			
	CE**	Marei, Mohamed Gaber, Afinidad, (1993), 50(443), 55-8			
	CF**	Radinov, R. et al., Journal of Molecular Structure, (1987), 158, 99-108			
	CG**	Cecchi, L. et al., Farmaco, Edizione Scientifica, (1983), 38(1), 24-8			
	CH**	Cecchi, L. et al., Farmaco, Edizione Scientifica, (1982), 37(2), 116-22			
	CI**	<del>Gestapo, A. et al., Journal of Heterocyclic Chemistry, (1979), 16(6), 1141-5</del>			
	CJ**	Kocevar, M. et al., Journal of Heterocyclic Chemistry, (1978), 15(7), 1175-84			

TOSHI, K.

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Examiner Signature	Date Considered
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RC